

### Remarks

Claims 1 - 11 were pending in the application. By this amendment, Applicants have amended Claims 1, 3, and 11, and canceled Claims 2, 4, 5, and 7. New Claim 12 has been added without introducing new matter. Claims 1, 3, 6, and 8 -12 remain pending. Claims 1, 11, and 12 are independent.

### *Claim rejections 35 USC § 102*

Claims 1, 2, and 8 - 10 stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 5,885,597 to Botknecht *et al.* Botknecht teaches a method of relieving pain using a topical composition including a local anesthetic as pointed out on page 2 of the Office Action. Following the Examiner's direction to column 3, line 54 to column 4, line 26, it is clear that Botknecht '597 teaches the combination of at least one corticoid analgesic, at least one arylpropionic acid type analgesic, and at least one p-aminobenzoic acid ester type local anesthetic, as well as an amount of capsaicin. Each of these compounds is, in and of itself, an active agent for alleviating pain. Botknecht '597 requires at least one of each of the four categories of pain relieving compounds in addition to capsaicin.

Applicants claimed method relates to the use of lidocaine for alleviating pain by producing an analgesia response without the development of anesthesia of the skin in which the patch is applied. Accordingly, Botknecht '597 simply does not teach or disclose a method using lidocaine as an analgesic (rather than an anesthetic).

Additionally, Applicants note for the record that Botknecht '597 does not indicate, in any way, that analgesia is achieved without anesthesia. In fact, Botknecht '597 only discusses the p-aminobenzoic acid ester type local anesthetic (lidocaine) as an anesthetic. Column 5, lines 46 - 65, indicates only that the local anesthetic is used. Further, this passage suggests, in relation to capsaicin, that the anesthetic actually helps make the capsaicin content unexpectedly well tolerated, apparently from the induction of anesthesia at the point of application; as well known side-effect of capsaicin application to the skin is an intolerable burning sensation on the skin in which it is applied. As the Examiner will appreciate, the relief of pain (analgesia) without the uncomfortable feeling of numbness normally associated with the use of lidocaine, is a useful, and heretofore unknown, process.

Botknecht '597 simply does not teach a method of inducing analgesia without anesthesia including only lidocaine, as the active analgesic. Accordingly, Applicants respectfully request withdrawal of the 35 USC § 102 rejection.

### ***Claim Rejection 35 USC § 103***

Claims 1 through 11 stand rejected under 35 USC § 103(a) as being unpatentable over Botknecht '597 in view of U.S. Patent No. 5,866,157 to Higo. Applicants note that the Office Action frankly admits that Botknecht *et al.* "does not teach the use of a transdermal patch in the administration of lidocaine for pain relief." To overcome this deficiency, Higo '157 is applied in combination with Botknecht '597. However, Higo '157, like Botknecht '597 is completely silent with respect to the use of a local anesthetic to achieve analgesia to the exclusion of anesthesia.

Applicants claimed method clearly requires the production of analgesia without anesthesia.

In light of the utter silence with regard to any method for the production of analgesia without anesthesia, Applicants respectfully submit that the hypothetical combination of Botknecht '597 with Higo '157, and each reference alone, do not teach or suggest each and every element of the claimed invention. The prior art simply has not recognized the application of a lidocaine composition to produce analgesia rather than anesthesia.

Prior to Applicant's invention, those skilled in the art would not have looked to the use of local anesthetics to produce analgesia alone. There is no indication in the art that local anesthetics were effective, unless and until they produced anesthesia. Accordingly, those skilled in the art simply would not have contemplated the invention as presently claimed.

New Claim 12 is directed to a method using lidocaine as the only active pain

reliever, i.e. analgesic. No new matter has been introduced. Paragraphs [0021-0022] clearly indicate that lidocaine is used and that other active ingredients may be included. Thus, there is clear support for the use of lidocaine as the sole active ingredient or in combination with other pharmaceutical agents.

Applicants respectfully submit for the reasons set forth above, the claims as amended are patentable over the applied references. Accordingly, early reconsideration and allowance of all pending claims is respectfully requested.

Respectfully submitted,



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**Marked up version in the claims**

1. (Amended) A method for treating non-neuropathic pain comprising topically administering a composition containing ~~a local anesthetic~~ 4-6% lidocaine to a patient near a pain locus in an amount sufficient to produce analgesia without causing anesthesia.

3. (Amended) The method of claim 1 wherein said ~~local anesthetic~~lidocaine is applied from a transdermal patch.

11. (Amended) A method for treating non-neuropathic pain comprising the step of:

topically administering a transdermal patch containing a pharmaceutical composition consisting of 5% lidocaine as ~~an~~ the only active ingredient, and the remainder consisting of inactive pharmaceutically acceptable materials wherein said administration produces analgesia without anesthesia.

Kindly cancel Claims 2, 4, 5 and 7 without prejudice and without disclaimer of the subject matter therein.

**Please add the following new claim:**

12. (New) A method for treating non-neuropathic pain comprising topically administering a composition containing 4-6% lidocaine as the only active ingredient to a patient near a pain locus in an amount sufficient to produce analgesia without causing anesthesia.